

**Amendments to the Specification**

Please replace the paragraph beginning on page 50, line 24 with the following amended paragraph:

Co-administration of DT and a control DNA sequence (SEQ ID NO:1; CpG2: *TCCAATGAGCTTCCTGAGTCT*) failed to induce a detectable rise in the anti-DT titers. In contrast, addition of a DNA sequence containing an unmethylated CpG dinucleotide flanked by two 5' purines and two 3' pyrimidines (SEQ ID NO:2; CpG1 (immunostimulatory DNA): *TCCATGACCGTTTCCTGACGTT*) resulted in a detectable increase in the serum anti-DT IgG titer in 5 of 5 animals. Thus it appears that bacterial DNA containing appropriate motifs such as CPGs (6 KD) can be used as adjuvant to enhance delivery of antigen through the skin for induction of antigen specific antibody responses.

BSH 12/13/07 51-52  
Please replace the paragraph beginning on page ~~52~~, line 5 with the following amended paragraph:

The transcutaneous effect of transcutaneous immunization can also be detected by T-cell proliferation. BALB/c mice 6 to 8 weeks of age were shaved and anesthetized as described above for the "immunization procedure". On the day of immunization the backs of the mice were wiped with isopropanol. After the alcohol had evaporated (approximately 5 minutes), 100 µl of phosphate buffered saline (PBS) containing 100 µg of DNA (CpG1 or CpG2) and 100 µg of diphtheria toxoid (DT) was applied to the back for 90 to 120 minutes. Oligonucleotides were synthesized by Oligos Etc with a phosphorothioate backbone to improve stability. Removal of excess antigen was conducted as described in the "immunization procedure." The immunization was repeated 4 and 8 weeks later. Twelve weeks after the primary immunization draining (inguinal) LNs were removed and pooled from five immunized animals. The capacity to proliferate in response to media or antigen (DT) was assessed in a standard 4 day proliferation assay using 3-H incorporation as a readout. The results are shown in Table 7B. Co-administration of DT and a DNA sequence containing an unmethylated CpG dinucleotide

10/790,715

Application/Control Number: 10/790,715

Page 2

Art Unit: 1644

### EXAMINER'S AMENDMENT

1. An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.132. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

2. Authorization for the Examiner's amendment was given in a telephone interview with Ms. Sally Teng on 11/19/07.

3. IN THE CLAIMS:

In claim 260, line 1, after "is", insert - - an alcohol, - -, line 2, after "formulation,", insert - - a cream, - -.

Cancel claim 263.

BSH 12/13/07

In claim 264, line 2, delete, "DNA", insert - - nucleic acid encoding an antigen, - -.

BSH 12/13/07

In claim 288, line 2, after "of", delete "DNA", insert - - nucleic acid encoding an adjuvant, - -.

In claim 296, line 2, after "formulation,", insert - - a cream, - -.

Cancel claim 299.

In claim 300, line 2, delete "DNA", line 2, insert - - nucleic acid encoding an antigen - -.

In claim 324, line 2, after "of", delete "DNA", insert - - nucleic acid encoding an adjuvant - -.

Cancel claim 335.

In claim 336, line 2, delete "DNA", insert - - nucleic acid encoding an antigen - -.

In claim 356, line 2, after "of", delete "DNA", insert - - nucleic acid encoding an adjuvant - -.